

remedies which RUS may have pursuant to the loan contract.

Dated: December 21, 1999.

Jill Long Thompson,

Under Secretary, Rural Development.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. 99-050IF]

RIN 0583-AC65

Food Labeling; Nutrient Content Claims, Definition of Term: Healthy

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is extending until January 1, 2003, the effective date of the requirements that, to bear the claim "healthy" or any other derivative of the term "health," individual meat and poultry products can contain no more than 360 milligrams (mg) sodium, and that meal-type products can contain no more than 480 mg sodium.

DATES: *Effective date:* December 28, 1999.

Comment date: Written comments should be received by January 27, 2000.

ADDRESSES: Submit one original and two copies of written comments to the FSIS Docket Clerk, Docket #99-050IF, Room 102, Cotton Annex Building, 300 12th Street, SW, Washington, DC 20250-3700. All comments will be available for public inspection in the Docket Clerk's office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: William J. Hudnall, Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation; telephone (202) 205-0495 or FAX (202) 401-1760.

SUPPLEMENTARY INFORMATION:

Background

In the May 10, 1994 **Federal Register** (59 FR 24220), FSIS published a final rule to establish a definition of the term "healthy" or any other derivative of the term "health" and similar terms on meat and poultry product labeling. The final rule provided a definition for the implied nutrient content claim "healthy" for individual meat and poultry products and for meal-type products. The rule defined two separate timeframes in which different criteria

for sodium content would be effective. According to the regulations, the first timeframe would last through the first 24 months of implementation (i.e., through November 10, 1997), and the second would begin after the first 24 months of implementation (after November 10, 1997).

Before November 10, 1997, under §§ 317.363(b)(3) and 381.463(b)(3), for an individual meat or poultry product to qualify to bear the term "healthy" or a derivative of the term "health" on the labeling, the product could contain no more than 480 mg of sodium (first-tier sodium level): (1) Per reference amount customarily consumed (RACC) per eating occasion; (2) Per labeled serving size; and (3) Per 50 grams (g) for products with small RACC's (i.e., 30 g or less or 2 tablespoons or less). With regard to the last provision, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount of all nutrients, the per-50-gram criterion refers to the prepared form. After November 10, 1997, to qualify to bear this term, the product could contain no more than 360 mg of sodium (second-tier sodium level) per RACC, per labeled serving size, and per 50 g for products with small RACC's. Under 317.363(b)(3)(i) and 381.463(b)(3)(i), a meal-type product could contain no more than 600 mg of sodium per labeled serving size before November 10, 1997, and no more than 480 mg of sodium per labeled serving size after November 10, 1997.

Also in the **Federal Register** of May 10, 1994 (59 FR 24232), the Food and Drug Administration (FDA) published a final rule to define the term "healthy" under section 403(r) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 343(r)). FDA's rule also defined two separate timeframes in which different criteria for sodium content associated with the use of the "healthy" claim would be effective. FDA's rule established the same sodium levels that the FSIS rule established for two separate timeframes; however, the timeframes in FDA's rule were different (i.e., before January 1, 1998, and after January 1, 1998).

On December 7, 1996, FSIS received a petition from ConAgra, Inc., requesting that §§ 317.363(b)(3) and 381.463(b)(3) be amended to "eliminate the sliding scale sodium requirement for foods labeled 'healthy' by eliminating the entire second tier levels of 360 mg sodium requirements for individual foods and 480 mg sodium for meal-type products." As an alternative, the petitioner requested that the effective date of November 10, 1997 be delayed

until food technology can develop acceptable products with reduced sodium content, and until there is a better understanding of the relationship between sodium and hypertension.

In response to the petition, FSIS issued an interim final rule on February 13, 1998, (63 FR 7279) to amend §§ 317.363(b)(3) and 381.463(b)(3) to extend the effective date for the lower sodium standards associated with the term "healthy" until January 1, 2000. The extension of the effective date was intended: (1) To allow time for FSIS to reevaluate the standard, including the data contained in the petition and any additional data that the Agency might receive; (2) to conduct any necessary rulemaking; and (3) to allow time for industry to respond to the rule or to any change in the rule that may result from the Agency's reevaluation.

FDA also received a petition from ConAgra, Inc., requesting that the lower sodium standards associated with use of the term "healthy" be removed from the regulations. In the **Federal Register** of April 1, 1997 (62 FR 15390), FDA announced a stay until January 1, 2000, of the provisions relating to the lower sodium standards.

In its February 13, 1998, interim final rule, FSIS asked for data concerning the technological feasibility of reducing the sodium content of individual foods to 360 mg per RACC and of meal-type dishes to 480 mg sodium per labeled serving and for additional information or views on consumer acceptance of meat and poultry foods with such sodium levels. With regard to technological feasibility, the Agency asked for information about the availability or lack of availability of acceptable sodium substitutes, the difficulties in manufacturing different lines of meat and poultry products with lowered sodium levels, and the impact of these sodium levels on the shelf-life stability and the safety of the food. The Agency also asked for comments on other approaches to reduce the amount of sodium in meat and poultry products labeled "healthy."

FSIS received 20 responses to the interim final rule. The comments responding to the rule presented strong and opposing views on whether FSIS should let the second-tier sodium levels take effect. They also contained a significant amount of data relating to use of the term "healthy."

FSIS has reviewed the comments and has also made an independent assessment of the number of foods labeled as "healthy." Based on the information available, the Agency tentatively concludes that, in some cases, the second-tier sodium levels may

be overly restrictive, thereby eliminating a term that may potentially assist consumers in maintaining a healthy diet. The Agency has been unable to complete its reevaluation of the definition of the term "healthy" or to consider fully options that preserve the public health intent while permitting manufacturers to use this term on foods that are consistent with dietary guidelines.

FSIS has not completed its reevaluation of sodium levels associated with the term "healthy" in the time allowed by the February 13, 1998, interim final rule because of: (1) Other Agency priorities; and (2) the need to investigate independently the validity of the strong opposing positions expressed in the comments. Because FSIS needs additional time to consider whether to propose a change in the definition, the Agency is extending the effective date until January 1, 2003.

FSIS also recognizes, as mentioned in the petition, that manufacturers must begin very soon to revise the formulations and labeling, if they have not already done so, for those products that do not comply with the requirement that must be met after January 1, 2000, to bear the claim "healthy." FSIS needs time to consider the supporting and opposing positions and to conduct any necessary rulemaking on the issues raised.

Given these factors, the Agency is persuaded that it is in the public interest to extend the effective date of the provisions for the lower standards for sodium in the definition of "healthy." This action is being taken to: (1) Allow FSIS time to reevaluate the information that supports and opposes the petition, (2) conduct any necessary rulemaking to revise the sodium limits for the term "healthy," and (3) provide time for companies to respond to any changes that may result from Agency rulemaking.

In the **Federal Register** of March 16, 1999, FDA published a final rule that extended the stay of the provisions relating to the lower sodium levels associated with the term "healthy" until January 1, 2003 (64 FR 12886). FDA's reasons for extending the stay of these provisions were largely the same as those that FSIS set out above.

Interested persons may submit comments regarding the appropriateness of the basis for this extension of the effective date of the lower sodium standards in the definition of the term "healthy." FSIS encourages manufacturers who can meet the lower sodium levels for particular foods and still produce an acceptable product to

do so even as the Agency reevaluates the issues discussed.

Executive Order 12988

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA and PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA and PPIA, or, in the case of imported articles, that are not at such an establishment, after their entry into the United States.

This interim final rule is not intended to have retroactive effect.

If this interim final rule is adopted, administrative proceedings will not be required before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this interim final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

Executive Order 12866 and the Regulatory Flexibility Act

This interim final rule has been determined to be non-significant and was not reviewed by OMB under Executive Order 12866.

The Administrator has made an initial determination that this interim final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). This interim final rule will impose no new requirements on small entities.

FSIS needs additional time to evaluate the impact of further reducing limits on sodium contents of foods labeled as "healthy" to determine if the costs of such an action exceed the benefits. The petitioner requesting the extension has presented data to support that lowering the sodium content on foods labeled as "healthy" could result in fewer "healthy" foods being consumed or consumers adding table salt to improve the products'

palatability. In addition, the petitioner suggested that lack of available substitutes for sodium would impair the industry's ability to continue manufacturing "healthy" foods as currently defined. If these impacts were to occur, the rule would not have the intended effect of improving diets. Some commenters to the previous FSIS interim final rule agreed with the petitioner. In addition to these comments, other commenters provided arguments supporting the implementation of the lower sodium limits. Based on comments received, FSIS believes that further benefits could be achieved by lowering the sodium content of foods labeled as "healthy." However, FSIS has also determined that it is in the public interest to extend the effective date for the lower sodium standards in the definition of "healthy" to provide the Agency additional time to determine if the more restrictive limits would have a negative effect. Unless the effective date is changed, meat and poultry products labeled as "healthy" would have to meet the more restrictive sodium standards on January 1, 2000, which could possibly deprive consumers of these products.

Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629; February 16, 1994), "Federal Actions to Address Environmental Justice in Minority and Low-Income Populations," FSIS has considered potential impacts of this interim final rule on environmental and health conditions in low-income and minority communities.

The interim final regulations would not require or compel meat and poultry product establishments to relocate or alter their operations in ways that could adversely affect the public health or environment in low-income and minority communities. Further, this interim final rule would not exclude any persons or populations from participation in FSIS programs, deny any persons or populations the benefits of FSIS programs, or subject any persons or populations to discrimination because of their race, color, or national origin.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development are important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this interim final rule, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which

is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

Waiver of Proposed Rulemaking

In accordance with the Administrative Procedures Act, 5 U.S.C 553, it is the practice of the Administrator to offer interested parties the opportunity to comment on proposed regulations. However, the extended effective date in this interim final rule does not establish any new rules. In addition, this interim final rule must be published in the **Federal Register** prior to January 1, 2000, because that is the current effective date in the regulations. Therefore, the Administrator has determined that publication of a proposed rule is impracticable, unnecessary, and contrary to the public interest under 5 U.S.C. 553(b)(B). For the same reasons, the Administrator waives the 30-day delayed effective date under 5 U.S.C. 553(d).

Paperwork Requirements

There is no paperwork associated with this action.

List of Subjects

9 CFR Part 317

Food labeling, Meat inspection, Nutrition.

9 CFR Part 381

Food labeling, Nutrition, Poultry and poultry products.

For the reasons discussed in the preamble, FSIS is amending parts 317 and 381 of the Federal meat and poultry products inspection regulations as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority for part 317 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 317.363 [Amended]

2. Section 317.363 is amended by removing the phrase "through January 1, 2000" in paragraph (b)(3) introductory text and (b)(3)(i) and replacing it with "through January 1, 2003".

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451-470; 7 CFR 2.18, 2.53.

§ 381.463 [Amended]

4. Section 381.463 is amended by removing the phrase "through January 1, 2000" in paragraph (b)(3) introductory text and (b)(3)(i) and replacing it with "through January 1, 2003".

Done at Washington, DC, on: December 21, 1999.

Thomas J. Billy,
Administrator.

[FR Doc. 99-33530 Filed 12-27-99; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 391

[Docket No. 99-045F]

Fee Increase for Meat and Poultry Inspection Services

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is increasing the fees that FSIS charges meat and poultry establishments, importers, and exporters for providing voluntary inspection services, overtime and holiday inspection services, identification services, certification services, and laboratory services. These fee increases reflect the increased cost of inspection, the national and locality pay raise for Federal employees (proposed 4.8 percent effective January 2000), the increased laboratory costs, and the applicable travel and operating costs. The fee increases will be effective January 1, 2000. At this time, FSIS is not

amending the fee for the Accredited Laboratory Program.

EFFECTIVE DATE: January 1, 2000.

FOR FURTHER INFORMATION CONTACT: For information concerning policy issues, contact Daniel L. Engeljohn, Ph.D., Director, Regulations Development and Analysis Division, Office of Policy, Program Development, and Evaluation, FSIS, U.S. Department of Agriculture, Room 112, Cotton Annex, 300 12th Street, SW., Washington, DC 20250, (202) 720-5627, fax number (202) 690-0486.

For information concerning fee development, contact Michael B. Zimmerer, Director, Financial Management Division, Office of Management, FSIS, U.S. Department of Agriculture, Room 2130-S, 1400 Independence Avenue, SW., Washington, DC 20250, (202) 720-3552.

SUPPLEMENTARY INFORMATION:

Background

On November 10, 1999, FSIS published a proposed rule (64 FR 61223) to increase the fees that FSIS charges meat and poultry establishments, importers, and exporters for providing voluntary inspection services, overtime and holiday inspection services, identification services, certification services and laboratory services. FSIS provided 30 days for public comment, ending the comment period on December 10, 1999.

FSIS received one comment from a Canadian firm in response to the proposal. The concerns raised by the commenter addressed inspections performed by the Animal and Plant Health Inspection Service, and therefore, do not fall within the scope of this rulemaking.

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) provide for mandatory inspection by Federal inspectors of meat and poultry slaughtered or processed at official establishments. Such inspection is required to ensure the safety, wholesomeness, and proper labeling of meat and poultry. The cost of mandatory inspection (excluding such services performed on holidays or on an overtime basis) is borne by FSIS.

In addition to mandatory inspection, FSIS provides a range of voluntary inspection, certification, and identification services for meat and poultry. Under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*), FSIS provides these services to assist in the orderly marketing of various animal products and byproducts not subject to the FMIA